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Prescription Drug Marketing Act of 1987
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I appreciate this opportunity to speak before the FDA on behalf of compounding pharmacists and the many patients who benefit from compounded medications. The International Academy of Compounding Pharmacists ("IACP") represents the interests of over 1,300 compounding pharmacists. We are very concerned that FDA's December 3, 1999 final rule, if implemented as written, will have a devastating impact on the ability of compounding pharmacists to obtain the bulk drug ingredients necessary to make compounded medications. The lack of supply of drug ingredients will seriously affect the well-being of the tens of thousands of patients who require custom-tailored medical therapies - treatments that can only be obtained through compounding.

There are two critical points that I want to make. First, the FDA's new requirements impose an unnecessary and unreasonable burden on wholesale distributors and compounding pharmacists without furthering Congress' intent of safeguarding the public. Congress' objectives can be met through monitoring and enforcement of the existing regulatory safeguards, without the burden of repetitive record keeping and tracking which will not protect the public but will increase costs to distributors, pharmacies, and ultimately consumers. My second point is that Congress did not intend that the requirements set forth in FDA's final rule apply to bulk drug ingredients.

HEALTH CARE BENEFITS OF COMPOUNDING MEDICATIONS

The pharmaceutical industry began with the compounding of drugs and treatments by individual physicians and pharmacists. During the past century, manufacturers have made giant leaps forward in developing new treatments for a myriad of patient ailments. However, despite the many technological advances in the pharmaceutical industry, compounding remains a vital element of quality patient care. Compounding fills the gaps in treatment left by mass-produced drugs and chain drug stores.

The importance of compounded drug therapies to patient health is well documented. Each of us - as individual patients - reacts to medicines differently

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depending upon our own physical make-up. Some people, through allergies or other sensitivities, simply cannot tolerate standard drug formulations. Some patients need drugs that manufacturers have discontinued for economic reasons.

Compounding allows physicians and pharmacists, working together, to provide custom-tailored medications that are not commercially available to meet individual patient needs. For example, if a patient is allergic to a preservative or a dye in a manufactured product, the compounding pharmacist can prepare a dye-free or preservative-free dosage form. Children often refuse to take many medicines because of the taste. Compounding pharmacists can introduce flavoring ingredients into such drugs as antibiotics and anti-seizure medications, to make these necessary medical treatments palatable for children. Similarly, individuals such as hospice patients who have difficulty swallowing a capsule can instead be prescribed a compounded lozenge or a lollipop.

Compounding is also important in developing medical treatments that require individualized dosage strengths and product formulation. For example, compounded treatments are often used to develop safe and effective hormone replacement therapies for women, through the ability to alter strengths and product formulations (pills, topical gels, patches), for each individual woman's physical requirements. Drug companies do not, and cannot, provide the same type of patient-specific drug therapies.

Congress has recognized the important health benefits of compounded therapies, as demonstrated most recently by the passage of the 1997 Food and Drug Administration Modernization Act ("FDMA"). FDMA formally recognized the benefits that compounded medications play in treating the unique medical needs of patients. Through this legislation Congress specifically acknowledged that pharmacists will need to use bulk drug ingredients in compounding. Without bulk drug ingredients, most compounding is not possible.

IMPACT OF THE FINAL RULE ON WHOLESALE DISTRIBUTORS OF BULK DRUG INGREDIENTS

FDA's final rule will implement provisions of the Prescription Drug Marketing Act of 1987 ("PDMA"). Congress passed PDMA for two principal reasons: to protect American consumers from mislabeled, adulterated or counterfeit prescription drugs; and secondly, to protect fair competition in the pharmaceutical industry. To prevent the commercial distribution of damaged prescription drugs, Congress created a drug "pedigree" requirement. Those wholesale distributors of prescription drugs who are not deemed to be "authorized distributors" must provide a statement which details the distribution history - or pedigree - of the drug. An authorized distributor is defined as a distributor "with whom a manufacturer has established an ongoing relationship."

For the past 12 years the pharmaceutical industry has relied on an FDA guidance letter which interprets the PDMA pedigree provision as follows:

(1) an "ongoing relationship" can be established by demonstrating two transactions in any 24 month period to be evidence of a continuing relationship; and

(2) that an "unauthorized" distributor only has to trace the pedigree back to the last "authorized" distributor, not all the way back to the original manufacturer.

This guidance has served the public well. Over the past 12 years there has been no evidence of an increase in diversion of prescription drugs stemming from industry's following this guidance letter. Further, there has been no intervention by Congress to change the direction of this guidance letter - nor any indication from Congress that the current practice does not serve the public interest.

FDA now seeks to depart from 12 successful years of agency and industry practice by altering these two interpretations of the PDMA pedigree provision to: (1) require a written agreement between a manufacturer and distributor to establish an "authorized" distributor; and (2) require that any unauthorized distributor obtain a drug pedigree which traces a drug all the way back to the original manufacturer.

FDA's new requirements will create an insurmountable administrative burden for many wholesalers, and particularly for small wholesale distributors. FDA's final rule does not require authorized distributors to provide pedigree information to unauthorized wholesale distributors. This places small secondary wholesale distributors at distinct economic and competitive disadvantages by having to construct the pedigree of the drug back to the original manufacturer - which in many cases may not be possible. Under FDA's rule, an authorized distributor who chooses not to furnish this information can effectively put secondary distributors out of business.

The small wholesale distributors of bulk drug ingredients are left entirely at the mercy of manufacturers and major wholesalers. While the large manufacturers and wholesalers will engage in occasional transactions with small distributors for small amounts of selected products sufficient to satisfy FDA's present criteria for establishing an "ongoing relationship," those same companies are not likely to take on the additional paperwork, disclosure requirements, and regulatory burden imposed if separate written agreements are mandated for numerous products and numerous customers. The FDA final rule will allow large scale distributors to "cherry pick" which small distributors get to be "authorized distributors." Allowing the large manufacturers to have such a competitive advantage will not further Congress' goal of preventing the sale of damaged prescription drugs to American consumers. Rather it will thwart Congress' intent in leveling the competitive playing field for drug companies.

Further, the final rule will disrupt the already complex balance which exists between the large drug manufacturers and the small wholesale distributors and pharmacies. This can only adversely affect the supply of bulk drug ingredients to such small operations and to compounding pharmacists. Given the intense public concern over the costs of drugs, it is inexplicable why FDA would now initiate this anti-competitive, cost-increasing measure. Indeed, FDA appears to have done no meaningful analysis of the economic impact of this rule, or assessed its impact on small businesses.

IMPACT OF FINAL RULE ON COMPOUNDING PHARMACIES

FDA's application of the PDMA's pedigree requirements to the wholesale distribution of bulk drug substances and FDA's requirement of a written agreement to demonstrate an "ongoing" relationship between distributors will greatly restrict pharmacists' access to bulk drug ingredients used to compound individualized medications. The Small Business Administration's Office of Advocacy, in its comments to the rule, has pointed out that the implementation of FDA's final rule will adversely affect approximately 4,000 small wholesale distributors. The vast majority of bulk drug ingredients purchased by pharmacies come from small repackagers who in turn purchase these ingredients from small distributors. Because of these relatively small purchases, many wholesalers are unlikely to be listed as authorized distributors. This will trigger the need for pedigree information for each shipment, which they will get only with great effort or not at all.

Large manufacturers traditionally will not supply bulk drug ingredients directly to pharmacies. The sale of bulk ingredients to compounding pharmacists is typically a miniscule component of the typical "authorized distributor's" business. These manufacturers and wholesalers have no direct economic interest in ensuring that pharmacists continue to have access to bulk drug ingredients to compound medications. Further, the final rule requirements will increase the administrative burden of larger manufacturers if required to make separate documentation sufficient to confer authorized distributor status on a wholesale distributor. The increased administrative burden will raise the fixed costs for drug manufacturing - again resulting in an increase in overall drug prices.

The inability of these distributors to purchase bulk drug ingredients would risk the health of patients whose access to vital compounded medications would be seriously disrupted. Imposing pedigree requirements will mean the loss of more than 70% of the bulk drugs currently used in compounding. Taking into account the numerous areas in which drugs are routinely compounded - such as home-health centers and hospitals - this will affect 10,000 pharmacies and tens of thousands of patients will not be able to obtain medical treatment necessary for quality health care. Any benefits that could be gained through this rule - and IACP believes the benefits are illusory - would be substantially

outweighed by the public health costs, preventing patients from receiving the prescribed medications.

FDA'S FINAL RULE IS NOT CONSISTENT WITH CONGRESSIONAL INTENT

FDA's final rule does nothing to advance Congress' objective of preventing the diversion or damage of drugs in the chain of distribution for finished form prescriptions drugs. In fact, FDA's final rule is inconsistent with Congress' intent on three points

(1) Congress did not intend to include bulk drug ingredients;

(2) The impact of the final rule on small distributors of bulk drugs will effectively destroy the practice of compounding which is inconsistent with Congress' mandate in passing the 1997 FDMA;

(3) FDA's interpretation of the pedigree requirements will create a redundant layer of regulation which will not increase competition, as intended by Congress. Instead, it gives more power to the large manufacturers and will increase drug prices for consumers - both at the pharmacy level through lack of supply and from the large manufacturers through increased paperwork and regulation.

The final rule will have a devastating effect on pharmacy compounding, an effect which is entirely avoidable while still realizing the true intent of Congress. The legislative history is clear that Congress intended only that PDMA prevent diversion in the chain of distribution of finished prescription drugs - not bulk drug ingredients. This is evidenced throughout the legislative history of the PDMA which expressly references only problems associated with the distribution of finished form prescription drugs, and never mentions the diversion of bulk drug ingredients. FDA's application of the pedigree requirements of the PDMA to bulk drug ingredients is contrary to Congress' expressed intent in passing the PDMA.

In addition, FDA's burdensome requirements for the distributors of bulk drug ingredients are unnecessary. Sufficient quality control and antidiversion safeguards and penalties exist under current FDA record keeping, licensing, and GMP regulations to ensure that damaged, adulterated or counterfeit bulk drug ingredients are not processed into compounded medications for distribution to consumers.

CONCLUSION

FDA's application of these requirements to bulk drug ingredients is a significant and unwarranted departure from FDA and industry practice. The agency's interpretation of the PDMA's pedigree requirement to apply to bulk ingredients is contrary to

Congress' intent to apply the law to finished dosage form drugs. Most importantly, if the final rule is implemented as written, it will have a devastating effect on the patients who rely on compounded medications. The inability of pharmacists to compound drugs threatens the health of patients who require individualized therapies.

In closing, on behalf of the IACP, I request that the FDA final rule be amended so that it is consistent with Congressional intent to clearly indicate that the pedigree requirements apply only to distributors of finished form prescription drugs, not to the distribution of bulk drug ingredients. If FDA chooses to ignore the will of Congress, the rule should at least be consistent with industry practice over the past 12 years and allow an authorized distributor to be demonstrated by two or more transactions with a manufacturer or other authorized distributor during a 24 month period, and require that any pedigree information required of unauthorized distributors only go back to the last authorized distributor.